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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Catherine Verfaillie

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EXAMINER

QIAN, CELINE X

ART UNIT

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1636

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,716	Applicant(s) VERFAILLIE ET AL.	
	Examiner CELINE X. QIAN	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) 1-8, 10-17 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-20 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 2/11/09 is acknowledged. The traversal is on the ground(s) that a MAPC cannot be construed as a hematopoietic stem cells. Applicants assert that are shown to be non-embryonic stem cells having the ability to differentiate into cell types of all three embryonic germ layers, whereas a hematopoietic stem cell can only form hematopoietic differentiated progeny, which is mesodermal phenotype. Applicants thus conclude that Hatada reference does not disclose the claimed invention.

This argument have been fully considered but deemed unpersuasive for following reasons. The present specification does not define multipotent adult progenitor cell (MAPC) as a specific population of cells that are non-embryonic and has the ability to differentiate into all three embryonic germ layers. Although the term MAPC is used in the prior art to refer to a cell population from bone marrow which is CD34-, CD44-, CD45- and CD117-, and can differentiate into three embryonic germ layers, the term is also used to refer to other population of adult progenitor cells such as multipotent neural progenitor cells (see for example, Hsieh et al. PNAS, 2004. Vol. 101, no.47, pages 16659-16664. see page 16659, 1st col., line 1). As such, without a clear definition, the term "MAPC" encompasses all multipotent adult progenitor cells, such as the hematopoietic cells disclosed by Hatada. Moreover, hematopoietic stem cells not only differentiate into hematopoietic lineages, they are also known to have plasticity which can differentiate into hepatocytes and neural cells (endoderm and ectoderm), thus is

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multipotent. Therefore, claims of Group I-III lack unity of the invention because the special technical feature does not make a contribution over the prior art. Even if MAPC is refer to the specific population as alleged by Applicants, the special technical feature of the invention of Group I, MAPC comprising exogenously incorporated sequence, is disclosed by Furcht et al. (WO 01/11011A2), which discloses MAPC comprising exogenously introduced eGFP under oct-4 promoter (see page 28, 1st paragraph). Therefore, this special technical feature does not make a contribution over the prior art, and thus cannot link the invention as a whole to form a single inventive concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-8, 10-17 and 20 are withdrawn from consideration for being directed to non-elected subject matter. Claims 9, 18 and 19 are currently under examination.

Claim Objections

Claim 9 is objected to for depending on non-elected claim 6. This claim is also objected to for using the term "MAPC" which may stand for a number of different words. It is remedial to spell out the entire term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Lamming et al (Blood, 2002: 100(11): abstract number 2574).

Claim 9 is drawn to a recombinant MAPC produced by the method of claim 6. This is a product by process claim, which reads on the product, a multipotent adult progenitor cell that comprises exogenously introduced DNA sequence. Claim 18 is drawn to a genetically altered multipotent adult progenitor cell that comprises exogenously introduced DNA.

Lamming et al. disclose multipotent adult progenitor cell comprises transfected with DS-RED expressing plasmid, and long term expression of DS-RED in said cells (see page 655a, 1st col., lines 14-16). Therefore, Lamming et al. disclose the instantly claimed invention.

Claims 9, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jahagirdar et al (Blood, 2001. 98(11 part 1): 547a).

Jahagirdar et al. disclose MAPC isolated from b-gal transgenic ROSA26 mice, which is genetically altered MAPC that comprises exogenous DNA (see col.1, line 5). Jahagirdar et al. also disclose that said cells differentiated in vivo in NOD-SCID recipient mice (see col.1, lines 11-26). Therefore, Jahagirdar et al. disclose the instantly claimed inventions.

Claims 9, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Furcht et al (WO 01/11011 A2).

Furcht et al. disclose isolated genetically altered MAPC comprising DNA that expresses eGFP. Furcht et al. further disclose said cells differentiate into mesodermal cell types following expansion (see for example, page 40, 1st paragraph). Therefore, Furcht et al. disclose the instantly claimed invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636

